IN THE UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION

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| THOMAS E. SPRINGER, in his Capacity as Trustee of the Chapter 7 Bankruptcy Estate of ROCIO HERRERA-NEVAREZ | ) | |
| *Plaintiff,* | ) | Case No. 1:17-cv-03930<br>Honorable Matthew F. Kennelly |
| ETHICON, INC. and JOHNSON & JOHNSON | ) | |
| *Defendants* | ) | |

**AMENDED MEMORANDUM IN OPPOSITION TO DEFENDANTS' MOTIONS *IN LIMINE***

THOMAS E. SPRINGER, as Chapter 7 Bankruptcy Trustee of Rocio Herrera-Nevarez, 11-10270 Bankr. N.D. IL., by and through his attorneys, PHILLIPS LAW OFFICES and WAGSTAFF & CARTMELL LLP, in response and opposition to Defendants' Motions *in limine*, states as follows:

**RESPONSE TO DEFENDANTS' MOTION *IN LIMINE* NO. 3: to Preclude Plaintiff from "introducing evidence of post-implant revisions to the IFU and patient brochure."**

Defendants claim that the 2015 TVT-O IFU and patient brochure revisions are "subsequent remedial measures," necessitating the application of Rule 407 and barring any evidence of them. However, defendants' revisions to the IFU and brochures in this case fall outside of the exclusionary rule and their motion should be denied. The recent revisions to the TVT-O IFU are not properly characterized as "remedial conduct" and are therefore not barred by Federal Rule of Evidence 407. The court may admit evidence of subsequent measures for another purpose such as impeachment or—if disputed—proving ownership, control, or the feasibility of precautionary measures.

The TVT-O IFU is part of the design of the subject product in this case, and requires its own design validation process. *See* Exhibit A, Design Change notice for 2015 TVT IFU changes. In cases where the manufacturer places feasibility of alternative designs into controversy by taking the position that those changes do not render the product safer, and would not have prevented injury, evidence of a manufacturers remedial measures can be introduced for impeachment of a defense witness. *Dewick v. Maytag Corp.*, 324 F. Supp.2d 894, (N.D. Ill. 2004); *Ross v. Black & Decker, Inc.*, 977 F.2d 1178, 1185 (7th Cir. 1992). Here, the defendants have placed this issue into question by having their expert, Denise Elser, offer the opinion that the TVT-O IFU is adequate in providing information concerning the potential risks of the TVT-O to intended users. Ex. B, General TVT and TVT-O report of Dr. Dense Elser at 39. In a nutshell, in order to be a "remedial measure" the defendant has to first admit that the subsequent design change, in this case, the updated IFUs and patient brochures are in fact necessary to make the device safer, and defendants have taken the opposite position here, stating that the IFUs were at all times adequate to apprise users of the risks.

As a predicate to the application of Rule 407, the subsequent measures taken by a party must be "remedial." In this case, however, defendants' revisions to the TVT-O IFU were not remedial. As Ethicon's Medical Affairs Director, and 30(b)(6) witness on the issue of the 2015 IFU change, Martin Weisberg, M.D., testified repeatedly in deposition, the revisions to the 2015 TVT IFU were not "necessary" nor were the revisions made to enhance or improve the safety of the TVT or its IFU *See* November 12, 2015 Deposition of Martin Weisberg, M.D., at pp. 91-94, relevant excerpts attached hereto as Exhibit "C."[1]

Similarly, because defendants did not undertake revisions to the IFU to make the TVT-O or the IFU safer, the policy justifications behind Rule 407 are not implicated. The primary public policy ground in support of Rule 407 is to incentivize responsible parties to implement added safety measures without fear of reprisal that such measures will be later admissible to establish liability. That justification is missing in this case because, as Ethicon's own representative and designated expert in this case has testified, the revisions were neither necessary nor made to enhance safety of the TVT-O.

Further, Defendants' speculation that evidence of changes to the 2015 TVT-O IFU will require them to introduce evidence of the Canadian regulatory process is incorrect. There is no reason why any evidence regarding the Canadian regulatory process needs to be introduced in this case, just is there is no need for evidence of the FDA process to be introduced in this case. The fact that Canadian officials requested changes to the TVT-O IFU is further reason why Rule 407 does not apply in this case, as the policy goal of encouraging remediation would not necessarily be furthered by excluding the evidence when a regulatory agency asked the company to take corrective action. *In re Testosterone Replacement Therapy Products Liability Litigation*,

[1] Dr. Weisberg agreed that "From Ethicon's perspective, the information that was added to the TVT IFU was not necessary for any safety reason whatsoever"

2017 WL 231201 (N.D. Ill. 2017) at 1. *Citing, O'Dell v. Hercules, Inc.*, 904 F.2d 1194, 1204 (8th Cir 1990).

Here, the revisions to the IFU are highly relevant to plaintiffs' substantive and punitive claims for a number of reasons. Evidence of the IFU revisions is first indicative of the knowledge and notice of defendants had with respect to the TVT-O device, which touches upon the reasonableness of defendants' conduct with respect to the warnings and labeling of the device. Further, as discussed above, such evidence would be probative of defendants' anticipated defense that the TVT device remains on the market and the suggestion it is neither defective nor were the warnings inadequate. Moreover, the revisions to the IFUs and patient brochures are relevant on the issue of causation, and on the question of what prescribing physicians (or patients, in the case of patient brochures) would have done different at the time the TVT-O device was prescribed. *See, e.,g., Id*. at 2 To the extent that the Court finds any unfair prejudice under Rule 403, it does not substantially outweigh the highly probative nature of the evidence.

**RESPONSE TO DEFENDANTS' MOTION *IN LIMINE* NO. 4: to Exclude "in-court demonstrations or testing of exemplar devices"**

The actual TVT-O device is relevant to the issues in this case, including Plaintiffs' design defect and failure to warn claims. There is nothing more relevant than the product at issue in the case, and there is no good reason for prohibiting admission of an exemplar device into evidence. Plaintiff has no objection to the court prohibiting counsel for both parties from touching, handling or performing "tests" on the TVT-O or other devices for any other purpose than to show the jury and the court what the device(s) look like. However, witnesses who are qualified and trained to handle the device(s) in the manner in which it is actually intended to be handled, such as plaintiff's expert, Dr. Rosenzweig, should not be subjected to the same restrictions. Moreover, the court should not impinge on the province of the jury by prohibiting them from

taking the device into the jury room if it is a properly admitted piece of evidence, nor should the court influence how the jury is allowed to consider this piece of evidence.

**RESPONSE TO DEFENDANTS' MOTION *IN LIMINE* NO. 6: to Exclude "evidence or argument relating to other lawsuits against Ethicon, including those concerning Ethicon's other products"**

Plaintiffs agree that evidence of the other lawsuits, claims, or investigations would be "generally considered" inadmissible hearsay when those statements were offered to prove the truth of the matter asserted. Fed. Rule Evid 801. However, a "statement is hearsay only if it is offered to prove the truth of the matter asserted in the statement. There are many situations in which evidence of a statement is offered for a purpose other than to prove the truth of the matter asserted. One such situation is when evidence of a statement is offered to establish notice to or knowledge of a party. At trial, plaintiffs intend to offer such evidence for this very purpose: to establish that defendants were aware and had knowledge of the potential complications and problems with the TVT-O device. Thus, such evidence is not barred by Federal Rule of Evidence 801. Evidence of other lawsuits or investigations against or by defendants for transvaginal mesh products is relevant to plaintiffs' substantive claims and punitive damages claims. For example, evidence that defendants were aware of the product defects in the TVT-O device and their failures to warn plaintiff are relevant to plaintiffs' product defect and failure to warn claims. Such knowledge also bears directly on the issue of punitive damages, and whether defendants' conduct was "actuated by actual malice or accompanied by a wanton and willful disregard of persons who foreseeably might be harmed by those acts or omissions." N.J.S.A. § 2A:15-5.12(a).

In addition, to the extent that defendants contend that the TVT-O or other mesh products are generally safe for the public, that there are millions implanted or that more women benefit from the products than are harmed by them, plaintiffs should be permitted to introduce evidence

of other lawsuits, claims, or investigations to rebut those arguments. The jury should be told both sides of the story. That is, if defendants attempt to make this case a referendum on mesh or the TVT-O for all prospective users, they will have opened the door to plaintiffs discussing other women's injuries as described in other lawsuits. Such evidence will be used merely to rebut defendants' claims that the vast majority of women use mesh without complaint.

**RESPONSE TO DEFENDANTS' MOTION *IN LIMINE* NO. 9: to Exclude "evidence or argument relating to medical device reports, reports of adverse events furnished by physicians, summaries of those reports, and/or aggregate numbers of MDRs for TVT-O or any other product"**

Defendants assert that evidence of product adverse event complaints is inadmissible. Courts allow reports of other incidents involving the medical product in question, including but not limited to FDA incident reports.[2] The statute cited by Defendants (21 U.S.C. § 360i(b)(3)) applies on its face only to "user reports;" that is, reports made by doctors or medical facilities to the FDA. It does not apply to reports received by, or made to, the FDA by the manufacturer, which are addressed in the same statute. *See Hughes v. Boston Scientific Corp.*, 631 F.3d 762, 773 (5th Cir. 2011) (discussing statutory requirement for manufacturer to report serious injuries or device malfunctions). Irrespective of whether a report made to the FDA by a doctor or

[2] *See, e.g.*, *Toole v. Baxter Healthcare Corp.*, 235 F.3d 1307, 1313 (11th Cir. 2000) (district court properly admitted 270 complaints relating to defendant's silicone gel breast implant in plaintiff's case to establish notice of the product's defective nature); *Hahn v. Sterling Drug, Inc.*, 805 F.2d 1480, 1483 (11th Cir. 1986) (evidence of similar incidents involving ingestion of defendant's topical analgesic, including FDA report compiling statistics of other incidents, admissible for several purposes in product action); *Kehm v. Procter & Gamble Mfg. Co.*, 724 F.2d 613, 625-26 (8th Cir. 1983) (other incidents involving defendant's tampon admissible in products action for various purposes); *Worsham v. A.H. Robins Co.*, 734 F.2d 676, 688-89 (11th Cir. 1984) (district court's decision to allow testimony regarding similar injury-related lawsuits involving defendant's intrauterine contraceptive device affirmed); *Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1385-86 (4th Cir. 1995) (district court properly admitted FDA Drug Experience Reports and summaries relating to defendant's painkiller); *Golod v. Hoffman La Roche*, 964 F. Supp. 841 (S.D.N.Y. 1997) (Held: FDA Adverse Experience Reports and FDA computer printouts summarizing reports for defendant's drugs relevant to notice, and not inadmissible as hearsay); *Tyler v. Sterling Drug, Inc.*, 19 F.Supp.2d 1239, 1241 (N.D. Okla. 1998) (anecdotal reports of product injuries admissible for notice, failure to warn, and causation); *Arrow Int'l, v. Sparks*, 98 S.W.3d 48, 53-54 (Ark. Ct. App. 2003) (trial court properly allowed evidence of 36 Medical Device Reports filed pursuant to FDA regulations regarding similar device malfunctions in wrongful death action); *Mahaney ex rel. estate of Kyle v. Novartis Pharm. Corp.*, 835 F. Supp. 2d 299, 311-13 (W.D. Ky. 2011) (FDA Adverse Drug Experience Reports relevant to show notice and medical causation).

medical facility would itself be deemed inadmissible, pursuant to 21 U.S.C. § 360i(b)(3), the fact that Defendants had notice of a complication involving the product in question is undeniably relevant and admissible.

Earlier accidents that occurred under circumstances substantially similar to those that led to a plaintiff's accident are relevant to whether a defendant had notice of a particular defect or danger, so such earlier occurrences are usually admissible under Rule 402. *Mihaliovich v. Laatsch*, 359 F.3d 892, 908 (7th Cir. 2004). Evidence of other incidents is admissible for several purposes, including "to show a defendant's notice of a particular defect or danger, the magnitude of the defect or danger involved, the defendant's ability to correct a known defect, the lack of safety for intended uses, the strength of a product, the standard of care, and causation." *Reid v. BMW of N. Am.*, 464 F. Supp. 2d 1267, 1271 (N.D. Ga. 2006). Indeed, "few things could be more relevant in a products action than the occurrence or non-occurrence of other accidents or failures under similar circumstances." *Rhodes v. Michelin Tire Corp.*, 542 F. Supp. 60, 62 (E.D. Ky. 1982).

Defendants' Motion is also contravened by their own argument and proffered expert testimony, wherein Defendants have asserted that there were only a small number of related complaints. Defendants cannot expect to argue misleadingly to the jury that the rate of TVT-O complications was low, while simultaneously preventing the jury from learning the truth: that literally thousands of women have suffered serious injury from the TVT-O product.[3] Therefore, Defendants' Motion should be denied

[3] *See, e.g., Worsham*, 734 F.2d at 688-89 (company doctor's testimony that there was no evidence that its products were dangerous opened the door to him being cross-examined about several other lawsuits against the company involving the same product-related injuries); *Green v. Schutt Sports Mfg. Co.*, 369 Fed. App'x 630, 638 (5th Cir. March 16, 2010) (evidence of similar injuries caused by similar products admissible based on manufacturer's defense that the plaintiff's conduct, not its product, caused injuries).

**RESPONSE TO DEFENDANTS' MOTION *IN LIMINE* NO. 11: to Exclude "Brian Luscombe's internal marketing presentation, the 'Top Ten Reason [sic] to Pursue … Gynecare TVT Obturator System.'"**

Defendants seek to exclude a document that pertains to the device at issue (the TVT-O), was created by Defendants, and was shown to its sales representatives as a part of their training on how to market the TVT-O to physicians. Defendants' only arguments in support of excluding this relevant and admissible evidence is that the risk of prejudice substantially outweighs any probative value of that presentation" This was not, as Defendants' claim, "one particular Ethicon employee['s]…poor attempt at humor" (Defs' Brf. at 8)—and even if it was, it would still be relevant and admissible. By Defendants' own admission, this was a corporate document shown to sales representatives in the course of their training.[4] *Id*. at 9. It contains information regarding: (1) the potential benefits that Ethicon (through its sales representatives) was claiming about the device; and (2) the reasons why Defendants developed the TVT-O in the first place. Moreover, it provides the jury with information relating to Defendants' training of its sales representatives with respect to the device at issue in this case. This evidence is relevant to Plaintiff's negligence and punitive damages claims. Not only is the PowerPoint relevant, but the probative value of the evidence outweighs any prejudice that Defendants now claim.[5] There is no "unfair" prejudice presented by this sales representative training document.

**RESPONSE TO DEFENDANTS' MOTION *IN LIMINE* NO. 12: to Exclude "evidence of any alleged complications associated with the device other than those alleged by Ms. Herrera-Nevarez"**

[4] This is not simply a tasteless email exchange between two Ethicon employees—it was part of their TVT-O training process.

[5] Under the Federal Rules of Evidence, admissibility of evidence is favored in doubtful cases. *Re-Tac Corp. v. J.W. Speaker Corp*., 212 F. Supp 164, 169 (E.D. Wis 1962). Evidence is unfairly prejudicial only to the extent it would cause the jury to decide the case on improper grounds. *United States v. Khan*, 771 F.3d 367, 377 (7th Cir. 2014).

As an initial matter, Plaintiffs do not concede that Ms. Herrera- Nevarez has not experienced groin pain, thigh pain, or leg pain. Dr. Rosenzweig's report notes that Ms. Herrera-Nevarez experiences pelvic pain due to the mesh, and that her prognosis for this is poor. Def. Ex. R, Rosenzweig report, at 25. Basic anatomy tells us that the pelvic region includes where the femur meets to form the leg. Further, Dr. Rosenzweig notes that the foreign body reaction of the TVT-O in the obturator membrane plays a role in the development of pain syndromes. *Id*. at 25-26. Moreover, with regard to mesh erosion and exposures, while Ms. Herrera-Nevarez has not yet experienced a mesh erosion or exposure in this case, Dr. Rosenzweig has noted in his general report that the chronic foreign body reaction and chronic inflammatory response of the TVT-O mesh leave the patient at lifelong risk of erosions. Ex. D, Rosenzweig General TVT-O report, 38. Further, Defendants' reliance on *In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4500767 is misleading and misplaced, as that was a *Daubert* ruling which only excluded testimony from a particular expert on two very limited adverse events: cancer and death. Defs' Brf. At 10. In fact, that order specifically allowed testimony regarding the term "chronic mesh pain syndrome", which is exactly the type of complication experienced by Ms. Herrera-Nevarez in this case, finding the term has been sufficiently demonstrated in the scientific literature. *Id*. Plaintiff's do not allege that cancer this case and will not seek to enter evidence relating to the possible carcinogenic properties of polypropylene at trial. As such, Plaintiffs do not contest Defendants' Motion to the extent it seeks to exclude evidence of any carcinogenic effect of the TVT-O, or polypropylene in general.

The more important part of Defendants' Motion, the part which Plaintiffs contest outright, is Defendants' request for a wholesale exclusion of all "evidence of any alleged complications associated with the device other than those alleged by Ms. Herrera-Nevarez."

Defs' Brf. At 9. That request is contrary to Illinois law in that it prevents the jury from conducting a "balanced" risk-utility assessment or determining the sufficiency of Defendants warnings and labeling for the TVT-O. Indeed, evidence of "other" known risks and complications is directly relevant to Plaintiffs' design defect and failure to warn claims.

Under Illinois law, the risk-utility (or risk-benefit) analysis requires the jury to consider all known risks and complications of a device. Specifically, under the risk-utility analysis, a product is "unreasonably dangerous" when the evidence establishes that "*on balance* the benefits of the challenged design outweigh the risks of danger inherent in such designs." *Lamkin v. Towner*, 563 N.E.2d 449, 457 (Ill. 1990) (emphasis added).[6] If the jury is not informed of *all* the potential risks and complications of the device—regardless of whether those risks manifested in Ms. Herrera-Nevarez—then it cannot possibly "balance" those risks against the claimed-benefits[7] of the TVT-O "as a whole" and determine the "overall safety" of the device.

Additionally, the Plaintiff in this case has a triable failure to warn claim. Under Illinois law, the jury must consider all known risks and complications associated with the TVT-O in order to determine whether the warnings were accurate and sufficient. *Hammond v. N.Am. Asbestos Corp.*, 454 N.E.2d 210, 216 (Ill. 1983) (holding that a manufacturer has a duty to warn of "*a product's dangerous propensities*" and a product "may be found defective and unreasonably dangerous to the user or consumer if the manufacturer or seller fails to adequately warn of *the potential risks or hazards associated with its use*.") (emphasis added). Moreover,

[6] A jury asked to apply the risk-utility test must consider all of the risks associated with a product's design and whether those risks, taken together, outweigh the utility of the product. *Mikolajczyk v. Ford Motor Co.*, 901 N.E.2d 329, 352 (Ill. 2008) (jury must consider the "overall safety" of the design and "whether the foreseeable risks of harm of the design outweighed its benefits"). The inquiry is a broad one, calling on the jury to consider a long list of nonexclusive factors, including the "usefulness and desirability of the product—its utility to the user and to the public *as a whole*" and "the collateral safety of [] feature[s] other than the one[s] that harmed the plaintiff." *Calles v. Scripto-Tokai Corp.*, 864 N.E.2d 249, 264-66 (Ill. 2007) (emphasis added).

[7] Defendants will surely seek to enter evidence of "benefits" of the TVT-O that Mrs. Herrera-Nevarez did not experience.

Defendants have raised the learned-intermediary doctrine as a defense to Plaintiffs' failure to warn claims. Under Illinois law, doctors who receive insufficient warnings "cannot be considered 'learned intermediaries.'" *Giles*, 500 F. Supp. 2d at 1068 (*citing Hansen*, 764 N.E.2d at 43). As such, *all* known complication and risks—whether or not they manifested themselves in Mrs. Herrera-Nevarez—are relevant and necessary to the jury's determination of: (1) the sufficiency of Defendants' warnings for the TVT-O; and (2) whether Dr. Vassallo was made sufficiently knowledgeable regarding these risks and complications to qualify as a "learned-intermediary."

**RESPONSE TO DEFENDANTS' MOTION *IN LIMINE* NO. 15: to Exclude "certain emails as irrelevant, prejudicial, and hearsay."**

Defendants seek to exclude two email strings identified in Defendants' Motion (Defs' Exs. T and U) as irrelevant, and allege that their admission would result in unfair prejudice, juror confusion, and undue delay. Defs' Brf. at 10-11.Defense Exhibit "T" is highly relevant and probative of the Ethicon's knowledge that the mesh was degrading in the package, even before it reached the customer and was implanted in the patient. This is extremely probative in this case as Ms. Herrera-Nevarez alleges that the complications she experienced are as a result of the degradation of the TVT-O mesh. Def. Ex. R, Rosenzweig report, at 26. Defense Exhibit "U" is likewise highly relevant and probative, because it discusses Ethicon's knowledge that complications, including erosions and fistulas, were common with polypropylene mesh, despite assertions by their experts that complications are common.

Defendants' also allege that the Exhibits "T" and "U" are hearsay. Plaintiff submits that these documents not hearsay as they are not being offered for the truth of the matter asserted, they are being offered for the purpose of showing knowledge and notice to the company that they were receiving report that the TVT-O mesh degrades, and that complications are common and

not rare. Second, even if the documents contains hearsay, they fall within a clearly defined hearsay exception as they are business records: they were kept in the course of regularly conducted business, and were made at or near the time by someone with knowledge.[8] Defendants allege that they are not business records under Federal Rules of Evidence 803(6) because it was not a business duty of the declarant to record those e-mails, however, Defendants offer no legal or factual support for this position.

**RESPONSE TO DEFENDANTS' MOTION *IN LIMINE* NO. 17: to Exclude "Plaintiff from presenting photographic or video depictions of any mesh surgical procedures"**

Defendants seek further to exclude any photographic or video evidence of the TVT-O surgery itself on the grounds that it is irrelevant and prejudicial. Federal Rule of Evidence 402 holds that "relevant evidence is admissible." Rule 401 defines evidence as relevant if "it has the tendency to make a fact more or less probable than it would be without the evidence." Fed. Rule Evid. 401, 402.

As an initial matter, the visual depictions of the TVT-O surgery are germane to the issues in this case, including Plaintiffs' design defect and failure to warn claims. In large part, the issues in this case involve the "minimally invasive" surgical procedure for implantation of the TVT-O device, including the method of placement of the mesh through the obturator space. Further, the manner in which the device is implanted addresses the mechanism by which plaintiff was injured. For example, the videos Plaintiffs intend to demonstrate the implantation of the TVT-O device under tension, which leads to mesh deformation. Defendants' principle argument is that the mesh videos should be excluded because they are prejudicial simply because they are

[8] Exhibit "T" was authored by Dan Smith, an engineer on the TVT-O project who had a duty to respond to inquiries regarding engineering issues with the TVT mesh, and Exhibit "U" was authored by two Ethicon medical directors in performance of their duties to create a clinical expert report for Ethicon products, describing the incidence of polypropylene mesh erosion.

graphic. Many pieces of evidence in this case may be uncomfortable for the jury and Defendants. The fact that such evidence may be unpleasant is no basis to preclude this highly relevant evidence.[9] As Defendants fail to inform the court, such evidence has been deemed admissible by the federal MDL court in multiple cases and procedure videos played before the jury, including in the *Lewis* and *Huskey* cases. In addition, Plaintiffs intend to be judicious in their use of these videos before the jury and do not plan to show substantial lengths of such the videos.

**RESPONSE TO DEFENDANTS' MOTION *IN LIMINE* NO. 18: to Exclude "Evidence or argument regarding mesh devices not implanted in Ms. Herrera-Nevarez."**

Plaintiffs should not be precluded *in limine* from presenting evidence about the devices at issue in this motion. The blanket manner in which defendants seek to preclude evidence or argument concerning these devices makes an accurate determination of the relevance and admissibility of the evidence impossible. For instance,Contrary to Defendants' assertions, evidence concerning the TVT-Secur and Abbrevo devices should be permitted as they were technologically feasible safer alternative designs which were in development at the time of Ms. Herrera-Nevaraz's May 2005 procedure. For example, the laser-cut mesh used in the TVT-Secur and Abbrevo was being tested as early as 1998, and the design of the Abbrevo mesh, using less mesh in the obturator space, was being discussed as early as March of 2004 at a secret meeting between the TVT-O inventor, Jean DeLaval and representatives from Ethicon to address safety concerns with the TVT-O product which had been launched just 3 months earlier. See. Ex. E, minutes of March 29, 2004 meeting on TVT-O.

Moreover POP products, —such as Ethicon's Prolift, Prolift+M, and Prosima (and their components and materials)—is relevant to Plaintiffs' claims and admissible because: (1) the

[9] To the extent the Court deems necessary, Plaintiffs suggest that the Court may prepare the jury prior to the visual depictions with a "trigger warning" as to the contents of the photographs or videos.

products are substantially similar to the TVT-O product; (2) the evidence can show Defendants' notice of problems with the heavyweight, small-pore mesh used in the TVT-O; and (3) evidence relating to the materials used in POP devices is relevant to assist the jury in assessing possible alternative designs for the TVT-O. Moreover, the lighter-weight, larger pore meshes utilized in these products, specifically the Gynemesh PS and Ultrapro meshes were both available at the time of Ms. Herrera-Nevarez's implant Federal courts, including Seventh Circuit, have applied the substantial similarity doctrine to determine the admissibility of evidence of prior accidents and other incidents of product failures.[10] The substantial similarity test does not require that the proposed evidence be identical to the present case.[11] Courts have also held that the substantial similarity doctrine is less stringent when evidence is introduced to demonstrate notice or defendant's knowledge of a dangerous defect.[12] Evidence relating to POP devices (and the mesh used in them) is also relevant to demonstrate that a feasible alternative design was available at the time the TVT-O was sold. For instance, Ethicon's lightweight mesh, Ultrapro, was proposed for use in Prolift+M to reduce the incidence of chronic pain compared to heavier, smaller pore mesh like the Prolene mesh used in TVT-O. This evidence demonstrating the availability of lighter weight, larger pore, less dense polypropylene mesh—and Defendants' choice to use it in

[10] *See, e.g., Dewick v. Maytag Corp.*, 324 F. Supp.2d 894, 901 (N.D. Ill. 2004); *See also*., *Hershberger v. Ethicon Endo-Surgery, Inc.*, No. 10-cv-00837, 2012 U.S. Dist. LEXIS 45220 (S.D. W. Va. Mar. 30, 2012); *Jiminez v. DaimlerChrysler Corp.*, 269 F.3d 439, 456 (4th Cir. 2001); *Moulton v. The Rival Company*, 116 F.3d 22 (1st Cir. 1997).

[11] *See, e.g., Mutrie Motor Transp., Inc. v. Interchemical Corp.*, 378 F.2d 447, 450 (1st Cir. 1967) ("'[S]ubstantial identity' does not mean absolute identity."). Courts have also held that the substantial similarity doctrine is less stringent when evidence is introduced to demonstrate notice or defendant's knowledge of a dangerous defect. *See, e.g., Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1386 (4th Cir. 1995) ("prior incidents are admitted to prove notice; the required similarity of the prior incidents to the case at hand is more relaxed than when prior incidents are admitted to prove negligence. The incidents need only be sufficiently similar to make the defendant aware of the dangerous situation").

[12] *See, e.g., Benedi v. McNeil-P.P.C., Inc.*, 66 F.3d 1378, 1386 (4th Cir. 1995) ("prior incidents are admitted to prove notice; the required similarity of the prior incidents to the case at hand is more relaxed than when prior incidents are admitted to prove negligence. The incidents need only be sufficiently similar to make the defendant aware of the dangerous situation").

*other* pelvic-floor devices—directly relates to Plaintiffs' negligence and design-defect claims. Defendants' motion to exclude evidence or argument concerning devices not implanted in Ms. Herrera-Nevarez should be denied.

**RESPONSE TO DEFENDANTS' MOTION *IN LIMINE* NO. 19: to Exclude "Evidence or argument regarding post-sale company documents authored by Dr. Meng Chen"**

Defendants seek to exclude evidence or argument regarding post-sale company documents authored by Dr. Meng Chen. First, Defendants, mischaracterize Dr. Chen's testimony as being only an investigation on whether to update the TVT-O IFU with information regarding the risk of chronic dyspareunia. Dr. Chen's investigation was far broader than that, including updating the IFU to better reflect patient experiences regarding pain, pain with intercourse, erosion, extrusion exposure, as well as the frequency and severity of these adverse events. Defendants argument also ignores the fact that these changes to the IFU are relevant to the design defect claim in this case, as the IFU is part of the design of the TVT-O product, which has its own separate design history file, and has the goal of reducing residual risk from the product to "as low as reasonably possible" by providing an appropriate warning. Here, Defendants are not stipulating that updating the IFU to include stronger warnings about the type, nature, severity, and frequency of adverse events would have prevented Ms. Herrera-Nevarez's injuries, in fact, they are disputing it. Def. Brf. At 12-13. Therefore, any evidence about any later design changes Ethicon made to the IFU remains admissible. *See, Dewick v. Maytag Corp.*, 324 F. Supp.2d 894, (N.D. Ill. 2004); Ross v. Black & Decker, Inc., 977 F.2d 1178, 1185 (7th Cir. 1992).

Meng Chen's Discussions regarding updating the TVT-O IFUs to better reflect patient experiences regarding pain, pain with intercourse, erosion, extrusion exposure, as well as the frequency and severity of these adverse events is highly relevant to plaintiffs' substantive and

punitive claims. Further, as discussed above, such evidence would be probative of defendants' anticipated defense that the TVT device remains on the market and the suggestion it is neither defective nor were the warnings inadequate, and thus is admissible for impeachment purposes. *See, Pub. Serv. Co. of Ind., Inc. v. Bath Iron Works Corp*., 773 F.2d 783, 792 (7th Cir. 1985).

**RESPONSE TO DEFENDANTS' MOTION *IN LIMINE* NO. 20: to Exclude "Evidence or argument regarding the Johnson & Johnson Credo"**

Defendants seek to preclude any mention of the Credo. However, in their argument, Defendants only cite to cases that precluded experts from opining that the Credo was the "standard of care" or "standard of liability." The cases Defendants rely on did not hold that the Credo is irrelevant. Defendants argue to preclude the Credo because a jury could be confused by the Credo because they may believe it sets the standard of liability. Given that no expert will testify that the Credo alone sets the standard of liability, there is no potential for confusion. Defendants' approach to how it does business, as established by its Credo, is highly relevant to Plaintiff's claims of product defect, failure to warn, and conduct warranting a jury's consideration of punitive damages. Defendants' employees used the Credo in making business decisions, which would include decision-making regarding product research, development, marketing, and testing and whether to include complete and accurate information regarding risks and complications of product, like the TVT-O. Therefore, Defendants' Motion in Limine No. 20 should be denied.

Respectfully submitted:

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**CERTIFICATE OF SERVICE**

I hereby certify that on July 27, 2017 I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service.

Date: 7/27/17

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